



SpineShape.
The dynamic solution
for your back.
Technical information
to System IV



SpineShape System IV highlights

- Dynamic stabilization of lumbar vertebrae and intervertebral discs through flexible rods
- In most cases long-lasting pain relief without spinal fusion surgery and without postoperative medication
- The mobility of the lower spine is preserved
- Protection of adjacent vertebrae and discs from excessive wear and tear
- Rods with three levels of flexibility for optimal adaptation to the particular disease pattern
- Proven and gentle operation

In summary

- Degenerative diseases
- Lumbar spine (Th12 – S1)
- Lateral and medial approaches
- Dynamic stabilization
- Pedicular fixation

The stepped region of the Varistab™ exhibits a reduced profile to allow for an elastic coupling of the adjacent motion segment.

The SpineShape System IV consists of PCU (polycarbonateurethane) rods and titanium pedicle screws.

Implants

The rods

Rods exist in five versions. Straight standard rods are packed with one each and Varistab™ rods with two each.

The screws

Pedicle screws exist in 17 sizes available in sets packed with two each, including two normal clamp screws.

Rods are available as standard version (normal clamp screws) and Varistab™ (long clamp screws).



RODS FLEXIBILITY	TYPE	SCREWS THREAD LENGTH	THREAD DIAMETER
high-flex	prismatic (standard rod)	40 mm	5.4 mm
mid-flex	prismatic (standard rod)	45 mm	5.4 mm
low-flex	prismatic (standard rod)	50 mm	5.4 mm
mid-flex	stepped (Varistab™)	40 mm	6.2 mm
low-flex	stepped (Varistab™)	45 mm	6.2 mm
		50 mm	6.2 mm
		55 mm	6.2 mm
		35 mm	7.0 mm
		40 mm	7.0 mm
		45 mm	7.0 mm
		50 mm	7.0 mm
		55 mm	7.0 mm
		35 mm	7.8 mm
		40 mm	7.8 mm
		45 mm	7.8 mm
		50 mm	7.8 mm
		55 mm	7.8 mm

Indications

- (Dynamic) stenosis
- Facet joint syndrome / Spondyloarthritis
- Osteochondrosis Modic Type I or III
- Discopathy (recurrent disc prolapse / herniation)
- Late adjacent segment syndrome
- Complement to disc prosthesis
- Osteochondrosis Modic Type II
- Degenerative spondyloarthritis (Meyerding <1)
- (Degenerative) Scoliosis (early stage – non rigid)
- Instability *
- Complement to cage **

HIGH-FLEX	MID-FLEX	LOW-FLEX
•	•	
•	•	
•	•	
	•	
	•	
	•	•
	•	•
	•	•
	•	•
	(•)	(•)

Note

The flexibility also varies with the distance between the pedicle screws. The further apart the screws, the more flexibility is achieved.

*) hypermobility with antelisthesis / hypomobility with retrolisthesis when decompressed
 **) treatment with SpineShape feasible but not preferred

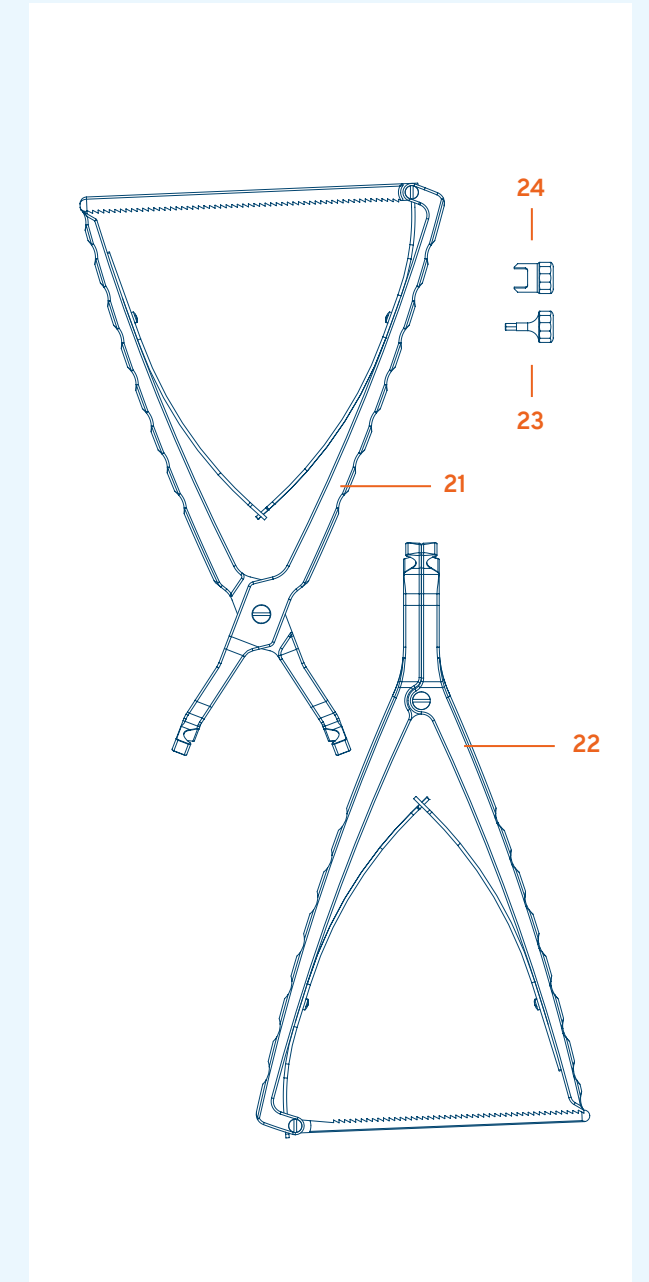
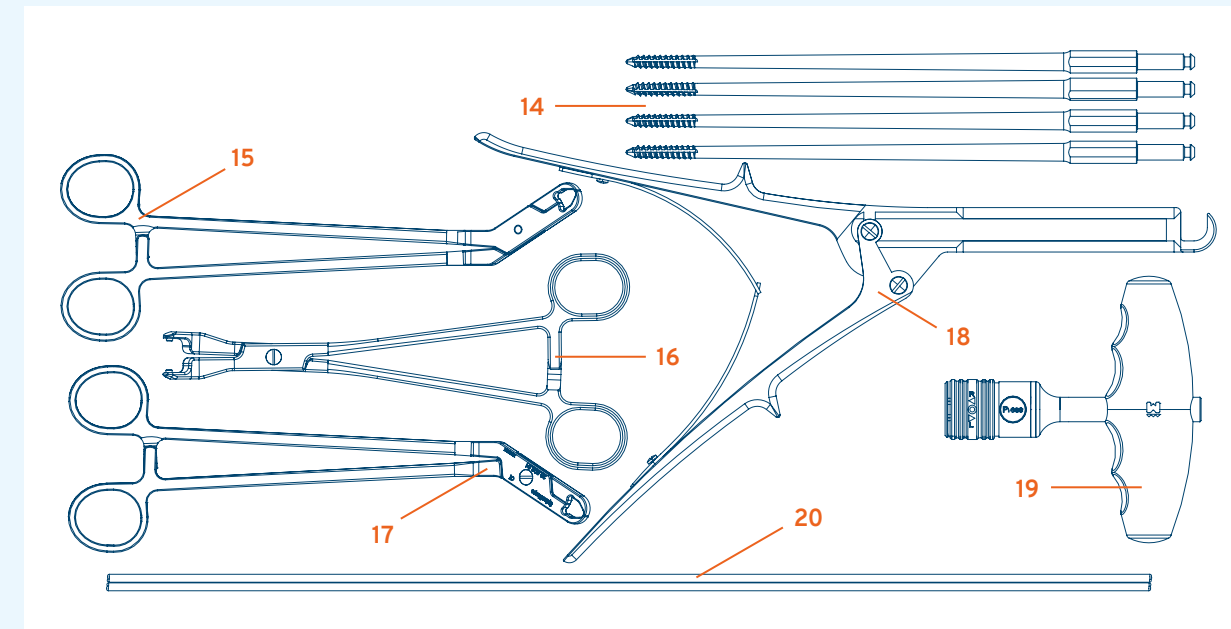
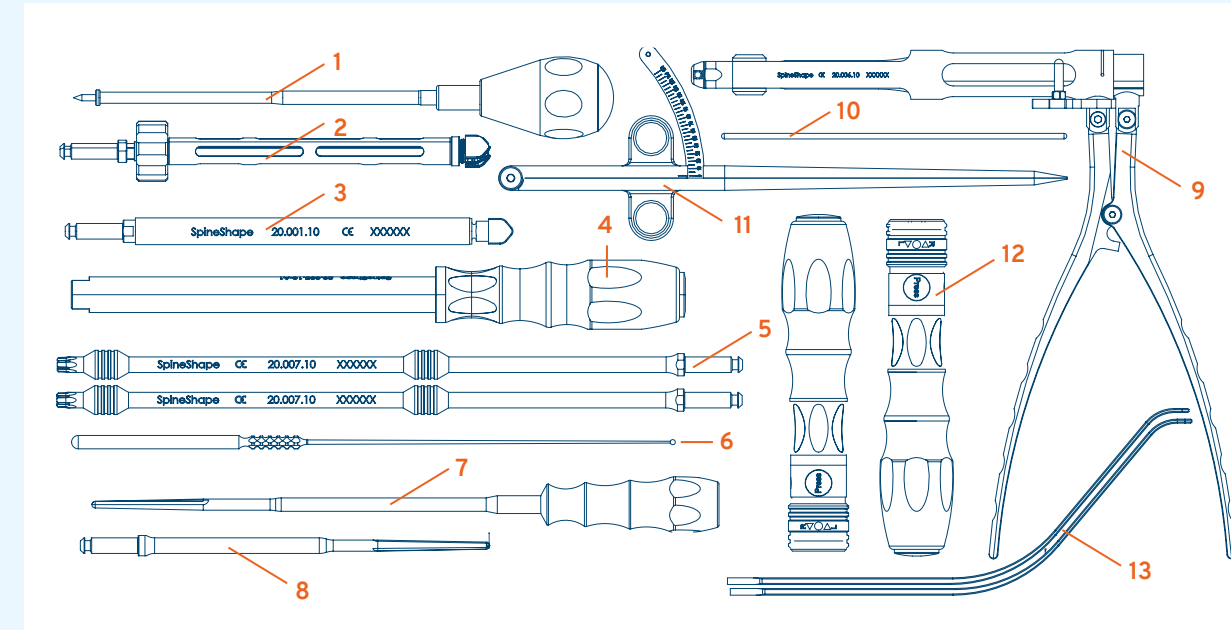
Contraindications

- Lack of or damaged structural tissues (e.g. vertebrae, intervertebral discs, facet joints, ligaments etc)
- Marked idiopathic scoliosis
- Spondylolisthesis > Meyerding grade 1
- Isthmic spondylolisthesis
- Bone tumour
- Osteoporosis that could compromise the screw anchorage
- Patient suffering from infections
- Known allergic reactions to single elements contained in the implant materials used or combinations thereof
- Skeletal growth

Instruments

DESCRIPTION	PIECES
1 Square pointer	1
2 Pedicle screw setter (with thread lock)	1
3 Pedicle screw setter (with holding sleeve)	1
4 Counter torque sleeve	1
5 Clamp screw setter	2
6 Pedicle sounding probe	1
7 Awl	1
8 3-lip cutter	1
9 Universal instrument	1
10 Orienting wire Ø2.5 mm	1
11 Compass	1
12 Big universal handle with ratchet	2
13 Muscle retaining lever	2
14 Cannulated screw tap	1 each
15 Left rod holding pliers with bent ends	1
16 Persuader	1
17 Right rod holding pliers with bent ends	1
18 Rod cutting instrument	1
19 T-Handle with ratchet	1
20 Blunt wire Ø1.6 mm	6

DESCRIPTION	PIECES
21 Contracting pliers	1
22 Distracting pliers	1
23 Stud bolt adapter DYNESYS	1
24 Pedicle screw adapter DYNESYS	1



Benefits

- New INI system for faster implantation
- New universal instrument
- All instruments in one container

Medical conclusion

Our philosophy is to bring the spine back to physiological degeneration while maintaining the sagittal balance.

- Shorter operation times
- Patient doesn't feel the implant
- Faster rehabilitation
- Rare events of sacroiliac joint pain

Results

Working again. Full-time and pain-free

Our average patient is pain-free, takes no or only little medication and enjoys unlimited walking-time post-operatively. Most patients are able to work full-time again in their previous professions.

Clinical results from patient population treated from 2015 onward

The following data originates from two consecutive samples with 1 year follow-up and 3 years follow-up patients operated by one of our leading surgeons. Patient satisfaction was measured with the Visual Analogue Scale (VAS) for the assessment of the patients' pain perception. The longest overall follow-up is more than 5.5 years and with more than 800 patients operated so far.

8.0

PRE-OP

7.0

PRE-OP

Pre-op 15% / Post-op 50%

NO LIMITATION DUE TO SPINE

1.4

3 MONTHS

1.8

3 MONTHS

1 year 72% / 3 years 65%

NONE OR MILD

Pre-op 15% / Post-op 25%

30-60 MIN

1.9

1 YEAR

3.1

1 YEAR

1 year 28% / 3 years 35%

STRONG (NSAR)

Pre-op 15% / Post-op 15%

15-29 MIN

2.6

3 YEARS

2.0

3 YEARS

1 year 0% / 3 years 0%

OPIOIDS

Pre-op 55% / Post-op 10%

LESS THAN 15 MIN

VAS FOR SCIATICA

Pre-/Post-op comparison of patient satisfaction regarding level of sciatic back pain from a scale 0-10: 0-3 (excellent or good), 3-6 (fair) and >6 (poor).

VAS FOR BACK PAIN

Pre-/Post-op comparison of patient satisfaction regarding level of low back pain from a scale 0-10: 0-3 (excellent or good), 3-6 (fair) and >6 (poor).

POST-OPERATIVE MEDICATION

A slight increase in medication after 3 years is hypothesized to result from an increase in activity.

WALKING TIME AFTER 3 YEARS

All patients made a progress in walking time.



What patients say

The first time in 10 years
without pain killers

Walking without pain for the first
time in 10 years

Pain completely
disappeared

Standing upright without
pain for the first time in
six months

After being unable to work as a truck
driver for a long time, again pain-free
and able to drive

A few days after the operation,
completely pain-free and back
home again

I don't feel the
implant at all

After three conventional
surgeries I am pain-free
for the first time

SpineSave: The company behind SpineShape

Swissness. Precision. Fascination

The company SpineSave has dedicated itself to motion preservation implant systems and offers to the surgeon solutions, which on one hand are based on proven methods and on the other hand are featured with step-wise innovations.

Fascination and pioneering spirit

SpineSave combines 35 years of engineering experience in biomechanics with 25 years of experience in producing medical devices. Stefan Freudiger and Rolf Diener as the founders are allied by Swiss quality and precision thinking with fascination and the necessary pioneering spirit for the dynamic stabilization of the spine.

Pioneers in motion preservation

Stefan Freudiger and Rolf Diener are pioneers in providing dynamic spine system.



Rolf Diener was one of the first having been able to manufacture the conical high-strength pedicle screws.



Stefan Freudiger was among the first who have developed dynamic stabilization systems.



SpineShape System IV is the fourth system for which Stefan Freudiger is listed (co-) inventor.



“For us as a company,
SpineShape mirrors
both precision and
fascination.”

ROLF DIENER, CO-FOUNDER

**Do you have questions regarding
SpineShape System IV?
Don't hesitate to get in contact.**

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